Quarterly Surveillance Report
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Assessing Colorectal Cancer Screening Options

"Since several screening strategies have similar efficacy, efforts to reduce colon cancer deaths should focus on implementation of strategies that maximize the number of individuals who get screening of some type." [1]

"The best colorectal cancer screening test is the one a patient will comply with." [2]

The goal of screening, from both the clinical and public health perspectives, is to identify individuals at risk so disease can be prevented or found and treated at an early stage. Colorectal cancer is an ideal candidate for screening programs:

- Colorectal cancer is common in Montana: 475 people are newly diagnosed and 175 people die from it each year.[3] It is the third most common cancer in Montana, after prostate and lung cancer for men, and after breast and lung cancer for women.
- Nearly 80% of colorectal cancer could be prevented by screening methods that find and remove polyps and precancerous lesions.[4]
- Among Montanans with colorectal cancer, more than 95% survive at least five years if their cancer is diagnosed at the local stage, but only 15% survive at least five years if their cancer is diagnosed at the distant stage.[3]

The US Preventive Services Task Force and a combined expert panel of the American Cancer Society, the US Multi-Society Task Force on Colorectal Cancer, and the American College of Radiology have both recently released evidence-based recommendations about all available forms of colorectal cancer screening.[1,5] This report summarizes those recommendations.

There are currently two ways to approach screening for colorectal cancer:

- non-invasive stool tests that generally detect existing cancer, ideally at an early stage:
  - ✓ guaiac-based fecal occult blood tests (gFOBT)
  - ✓ fecal immunochemical tests (FIT)
  - ✓ stool DNA tests (sDNA)

[1] US Preventive Services Task Force. 2008. Screening for Colorectal Cancer. Recommendation Statement. Available at www.ahrq.gov/clinic/uspstf08/colocancer/colors.htm
[2] Personal communication from Montana physician
[3] Cancer in Montana 2002-2006, Montana Central Tumor Registry Annual Report, June 2008. Available at www.cancer.mt.gov
[4] Maciosek MV et al., 2006. *Am J Prev Med* 31:80-89.
[5] Levin B et al. 2008. *CA Cancer J Clin* 58:130-160.

- direct examination tests of varying degrees of invasiveness that inspect part or all of the colon, aimed at primary prevention of colorectal cancer by detecting and removing polyps and precancerous lesions:

  - ✓ flexible sigmoidoscopy of the lower third of the colon
  - ✓ colonoscopy of the entire colon
  - ✓ double contrast barium enema of the entire colon (DCBE)
  - ✓ computed tomographic colonography of the entire colon (CTC)

The authors of the current screening guidelines[1,5] expressed the strong opinion that prevention is the preferred goal, but also recognized that some people are unwilling or unable to participate in the direct examination procedures. Personal preference, inadequate health care coverage, and limited access to specialized facilities will continue to be barriers for some people. The guidelines emphasize that all adults age 50 years and older at average risk should participate in some form of screening.

Stool testing was endorsed with stringent caveats:

- Providers and patients must recognize that stool tests generally detect existing cancer; they rarely detect precancerous lesions or contribute to the prevention of progression of such lesions to cancer.

- Providers should offer only high-sensitivity stool tests (see next page).

- Patients must be willing to comply with the requirements of sample collection to yield accurate results.

- Patients must be willing to comply with annual testing.

- Providers should have an office system to remind patients about the need for annual testing and to follow up positive test results.

- Positive stool tests should be followed up with colonoscopy, not a second stool test.

Sensitivity and Specificity

Sensitivity is the ability of a test to give a positive result in the presence of disease. If a test has a sensitivity of 68%, it will give a true positive result in 68% of patients who have disease, but it will give a false negative result in 32% of patients who have disease. gFOBT and FIT tests may give false negative results because of inadequate sample collection or handling, or because a polyp, precancerous lesion, or cancer is not bleeding at the time of the test.

Specificity is the ability of a test to give a negative result in the absence of disease. If a test has a specificity of 75%, it will give a false positive result in 25% of people tested. gFOBT or FIT tests may give false positive results if a patient has blood in the stool from causes other than polyps or precancerous or cancerous lesions, or because the patient did not observe proper dietary restrictions before taking a gFOBT test.

For technical reasons, few screening tests can be both highly sensitive and highly specific.

Test Sensitivity and Program Sensitivity

Stool tests have only moderate sensitivity as one-time tests, but greatly enhanced sensitivity in program (consistent annual) testing. For a test with 68% sensitivity, a patient has a 32% risk of false negative result in the presence of colorectal cancer for any given annual test. For three consecutive annual tests, the overall risk of a false negative is only 3% (vis., 0.32 x 0.32 x 0.32 = 0.03). However, program sensitivity depends on adherence to annual testing requirements.

Choosing a Colorectal Cancer Screening Test

Colonoscopy provides the most direct assessment of the presence of cancer or precancerous lesions and polyps in the entire colon. The other screening tests have generally been evaluated in people scheduled to undergo colonoscopy, using the results of the colonoscopy as the gold standard against which the other test is rated. Table 1 (page 4) compares several characteristics of the approved colorectal cancer screening tests.

gFOBT or FIT may be attractive to patients for whom cost is a barrier to other forms of screening. The sensitivity of gFOBT and FIT tests varies by brand; providers should offer only the most sensitive tests.[6] sDNA tests are more expensive than gFOBT or FIT but may also be an option for individuals who resist direct examination methods. Patients who choose any stool test should be aware that they have a low potential for preventing colorectal cancer but can contribute to the detection of colorectal cancer at an early stage, thus reducing mortality, but only if repeated annually. Providers should have a system to facilitate adherence to annual testing and insure appropriate follow-up of positive results.

All of the direct examination methods with high potential for preventing colorectal cancer -- flexible sigmoidoscopy, double contrast barium enema (DCBE), computed tomographic colonography (CTC), and conventional colonoscopy -- are characterized by relatively high cost and the need for pretest bowel preparation. Both sigmoidoscopy and colonoscopy have some risk of bowel perforation and other serious complications (estimated at 40/100,000 and 250/100,000 procedures, respectively). Colonoscopy has the additional disadvantage of the need for sedation and its occasional rare complications. The risk of serious complications following DCBE is lower (approximately 4/100,000 procedures) but DCBE is becoming less available in many communities. CTC is a relatively new technology and not yet widely available. CTC requires bowel preparation, just as the other direct imaging techniques do, but it is otherwise the least invasive direct imaging procedure. Bowel distention with air is required and may rarely result in perforations (estimated at 30/100,000). In addition, CTC uses low-dose radiation. The radiation from a single CTC screening is below the threshold believed to be harmful for most adults, but the risk should be evaluated for each patient in light of cumulative radiation exposure from all diagnostic and therapeutic procedures.

All adults age 50 years and older at average risk of colorectal cancer should be screened according to guidelines. The choice of a screening test must be made after consideration of individual circumstances and preferences. No patient should be made to feel that direct examination tests are the only worthwhile options. If a patient cannot or will not participate in direct examination tests, stool tests can and should be recommended with appropriate counseling about the importance of pretest dietary restrictions if necessary, proper collection of the sample, and the need for annual testing.

[6] Levin B et al. 2008. *CA Cancer J Clin* 58:130-160 inlcudes an assessment of sensitivity of currently available stool tests.

Table 1. Comparison of Screening Tests for Colorectal Cancer

Test	Potential to prevent cancer	Single-test Sensitivity §	Sensitivity of three consecutive annual tests	Specificity §	Expected proportion of follow-up colonoscopies finding no cancer	Interval between normal screens	Estimated relative cost of tests	
							Cost per test †	Lifetime cost per patient ‡
gFOBT	Low	61% - 76%	94% - 99%	85%	15%	1 year	$20	$520
FIT	Low	78% - 89%	98% - 99%	87%	13%	1 year	$35	$910
sDNA	Low	49% - 87%	87% - 99%	93% - 97%	3% - 7%	1 year	$80	$2,080
Flex sig	High	57% - 67%	~	100%	¶	5 years	$300	$1,500
Colonoscopy	High	95% §	~	100% §	~	10 years	$1,600	$4,800
DCBE	High	46% - 90%	~	unavailable	unavailable	5 years	$500	$2,500
CTC	High	67% - 89%	~	86% - 97%	3% - 14%	5 years	$800	$4,000

§ Other tests were evaluated against colonoscopy; several studies estimate that colonoscopy may miss up to 5% of small lesions due to incomplete bowel preparation or variation in operator performance.

† Based on Montana's 2008 Medicare reimbursement schedule. Medicare reimbursement was chosen to compare relative costs because data were available for all test modalities. This provides an accurate ranking of costs but does not reflect total cost of each test, such as associated charges from physicians, pathologists, or laboratories.

‡ Assuming screenings are performed at prescribed intervals and all screenings are normal between ages 50 and 75 years, at current cost per test.

¶ All flexible sigmoidoscopies finding polyps or any malignancy should be followed by full colonoscopy to examine the remainder of bowel.

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